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Compounding Problems: Recent Decisions on Tirzepatide Highlight Interplay Between FDA Anti-Compounding Enforcement and Private Intellectual Property Rights

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Earlier this month, a federal district court denied the Outsourcing Facilities Association's preliminary injunction motion, which sought to preclude FDA from taking enforcement action against compounded tirzepatide products.[1] Tirzepatide is the active pharmaceutical ingredient in Eli Lilly & Co.'s blockbuster weight loss and diabetes drugs Zepbound and Mounjaro. The Outsourcing Facilities Association, a trade association representing compounding pharmacies, challenged FDA's October 2, 2024 decision to remove tirzepatide from the drug shortage list established under Section 506E of the Federal Food, Drug, and Cosmetic Act ("FD&C Act"). The Section 506E drug shortage list permits otherwise prohibited compounding use of certain pharmaceutical ingredients (or "drug substances") when FDA determines that a qualifying need exists.[2]

The Outsourcing Facilities Association argued that FDA's delisting decision was a substantive rule that should have undergone formal notice-and-comment rulemaking. The court held, however, that FDA's decision to add or remove drugs from the Section 506E list is an informal adjudication. Significantly, shedding formalities allows FDA to "maintain an up-to-date list," required under Section 506E, by enabling relatively expeditious responses to changes in availability and demand for drugs. Treating such listing decisions as informal adjudications is

also a two-way street: compounders previously *benefited* from FDA's speedy determination that a shortage of tirzepatide existed.

Importantly, FDA's finding of a Section 506E drug shortage does not insulate compounders from patent and federal trademark infringement. For example, a contemporaneous court decision allowed Eli Lilly's federal trademark infringement and false advertising claims to proceed against compounders selling copies of Mounjaro and Zepbound.[3] In reaching this decision, the court explicitly found that the FD&C Act does not bar claims arising under the Lanham Act.[4] This outcome encourages stronger policing of trademarks against compounders who attempt to associate their compounded products with branded drug products. Likewise, pharmaceutical companies owning unexpired patents on a drug product's active ingredient, formulation, or use could have recourse against compounding copies.

These cases show two distinct paths to limit the compounding use of pharmaceutical ingredients: Sections 503A and 503B of the FD&C Act empower FDA to take enforcement action against unsanctioned compounding of drug products, and patent and federal trademark laws enable pharmaceutical companies to police unauthorized use of their intellectual property.

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[1] *Outsourcing Facilities Ass'n v. U.S. Food & Drug Admin.*, C.A. No. 4:24-cv-00953-P (N.D. Tex. Mar. 5, 2025).

[2] Sections 503A and 503B of the FD&C Act prohibit compounding products that are "essentially a copy" of commercially available drug products (under Section 503A) or use a qualifying active pharmaceutical ingredient (under Section 503B). The Section 506E drug shortage list exempts from this prohibition qualifying drug products that fill a commercial need.

[3] *Eli Lilly & Co. v. Alderwood Surgical Ctr. LLC*, C.A. No. 2:24-cv-00878 (W.D. Wash. Mar., 7, 2025).

[4] This decision does not permit, however, a private cause of action seeking to enforce compounding oversight provisions of the FD&C Act. Decisions out of the U.S. Courts of Appeal for the First Circuit and Ninth Circuit prohibit such usurpation of FDA's enforcement authority. *See Azurity Pharms., Inc. v. Edge Pharma, LLC*, 45 F.4th 479 (1st Cir. 2022); *see also Nexus Pharms., Inc. v. Cent. Admixture Pharmacy Servs., Inc.*, 48 F.4th 1040 (9th Cir. 2022); *Nexus Pharms. v. Quva Pharma, Inc.*, No. 20-56160, 2022 WL 4181714 (9th Cir. Sept. 13, 2022); *Nexus Pharms. v. Leiters Inc.*, No. 20-56158, 2022 WL 4181716 (9th Cir. Sept. 13, 2022) (consolidated before Ninth Circuit). In addition, the Lanham Act holding does not extend to claims arising under the trademark and unfair competition laws of U.S. states.

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